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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/555,918

10/05/2006

Heino Hermeking

460-37

4485

81099

7590

03/04/2009

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EXAMINER

GOSART, TIMOTHY J

ART UNIT

PAPER NUMBER

4118

MAIL DATE

DELIVERY MODE

03/04/2009

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/555,918	Applicant(s) HERMEKING, HEINO	
	Examiner TIMOTHY GOSART	Art Unit 4118	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 07 November 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-16 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-16 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>11/07/2005</u> . | 6) <input type="checkbox"/> Other: _____ |

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DETAILED ACTION

1. This office action is responsive to the amendment filed on November 7, 2005 . As directed by the amendment: claims 2-16 have been amended, no claims have been cancelled and no claims have been added. Thus, claims 1-16 are presently pending in this application.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. The claims are generally narrative and indefinite, failing to conform with current U.S. practice. They appear to be a literal translation into English from a foreign document and are replete with grammatical and idiomatic errors.

4. Claims 1, 2, 4, 5, 6, 7, 8, 9, 10, 12, 14, 15, and 16 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

5. Regarding claim 1, the phrase "and/or" renders the claim indefinite because it is unclear whether the limitations following the phrase are part of the claimed invention. See MPEP § 2173.05(d).

6. Regarding Claim 2, the phrase "it" in Line 5 renders the claim indefinite because it is unclear which limitation the phrase is referring to.

7. Regarding Claims 4, 7, and 8, the limitation "the diaphragm" renders to the claims indefinite because it is unclear which of the three diaphragms (recited in claim 1) is being claimed.

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8. Regarding Claim 5, the phrase "the latter" in Line 8 renders the claim indefinite because it is unclear which limitation the phrase is referring to.

9. Regarding Claim 6, the phrase "wherein least one straight fold line" renders the claim indefinite. The phrase is interpreted as "wherein at least one of the fold lines is a straight fold line."

10. Claim 9 recites the limitation "the elastic material" in Line 3. There is insufficient antecedent basis for this limitation in the claim.

11. Claim 10 recites the limitation "the planar elements" in Lines 2-3. There is insufficient antecedent basis for this limitation in the claim.

12. Claim 10 recites the limitation "the division" in Line 4. There is insufficient antecedent basis for this limitation in the claim.

13. Claim 12 recites the limitation "a foldable fixation ring" by inferential inclusion. It is unclear whether the limitation is part of the claimed invention.

14. Regarding claim 14, the phrase "particularly lens for an iris prosthesis system according to claim 1" renders the claim indefinite because it is unclear whether the limitation(s) following the phrase are part of the claimed invention. Specifically, it is unclear whether the limitations of Claim 1 are part of the lens of Claim 14. See MPEP § 2173.05(d).

15. Further regarding Claim 14, the phrase "that" in Line 4 and Line 5 renders the claim indefinite because it is unclear which limitation the phrase is referring to.

16. Regarding Claim 15, the limitation "the diameter of the lens body is greater than that of the anchoring part" is improperly dependent on Claim 14 which has the limitation "an anchoring

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part...having a greater diameter [than the lens body]." The limitations are mutually exclusive.

Claim 15 is interpreted as being dependent on Claim 1.

17. Regarding claim 16, the phrase "particularly dyed with pigment dye" renders the claim indefinite because it is unclear whether the limitation(s) following the phrase are part of the claimed invention. See MPEP § 2173.05(d).

18. Claim 16 recites the limitation "the lens" in Lines 4-5. There is insufficient antecedent basis for this limitation in the claim.

19. Further regarding claim 16, the phrase "preferably" renders the claim indefinite because it is unclear whether the limitation(s) following the phrase are part of the claimed invention. See MPEP § 2173.05(d).

Claim Rejections - 35 USC § 102

20. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

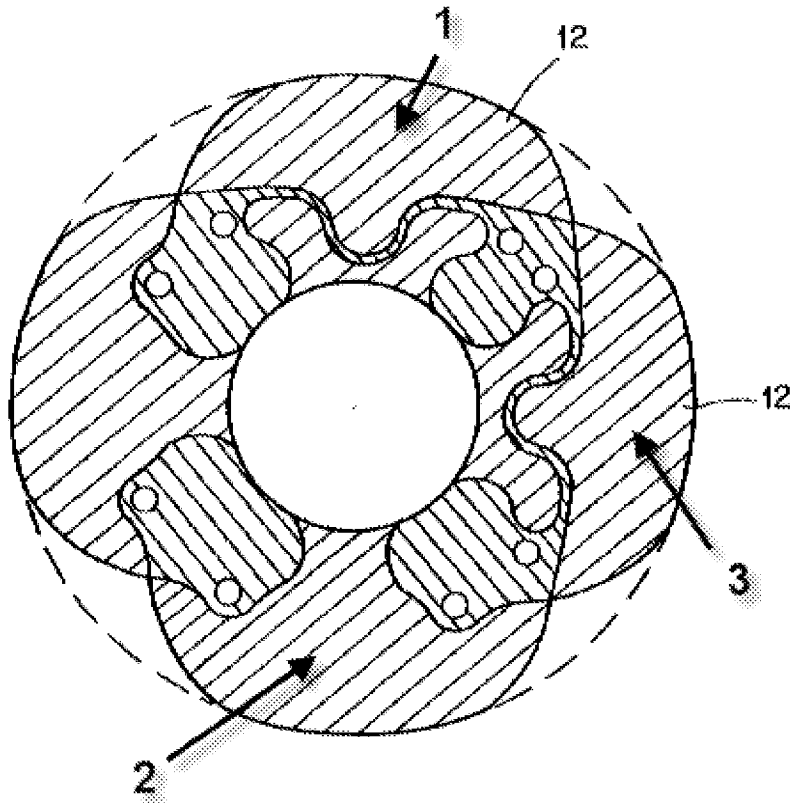
A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

21. Claims 1-4 and 9-13 are rejected under 35 U.S.C. 102(b) as being anticipated by Hermeking (US 6221106).

22. Regarding Claim 1, Hermeking discloses an iris prosthesis system with at least three diaphragms (Figure 4, below) that create an artificial pupil in the anterior section of the eye (Abstract) and which are compressible and foldable (Column 5, Lines 18-23) and therefore capable of being implanted using methods known in the art.

FIG. 4



23. Regarding Claim 2, Hermeking discloses the diaphragm as having a coverage region 10, central aperture 16, and stirrup-shaped haptic 20 (Figure 7).
24. Regarding Claim 3, Hermeking discloses the haptic as being C-shaped (Column 2, Line 8).
25. Regarding Claim 4, Hermeking discloses the diaphragm has an opening 24 for a needle tip or guide hook (Figure 7 and Column 2, Lines 22-23).
26. Regarding Claim 9, as best understood, Hermeking discloses the diaphragm as comprising silicone (Column 2, Lines 42-44).
27. Regarding Claims 10-11, as best understood, Hermerking discloses the diaphragm as being planar and comprising round holes 22 and 24 close to its edge (Figure 6).

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28. Regarding Claim 12, Hermeking discloses a fixation ring 30 (Figures 11-12) inserted into a central aperture of the diaphragm (Column 2, Lines 38-41). Hermeking also discloses stress-free implantation of the iris prosthesis system (Abstract), necessitating the fixation ring to be constructed of a foldable material in the same manner as the diaphragm. Further, the fixation ring is PMMA (Column 4, Lines 24-31), which is foldable (Column 5, Lines 17-21).

29. Regarding Claim 13, Hermeking discloses the diaphragm as being coupled to an artificial lens (Abstract) and being clipped to the central aperture of the fixation ring (Column 4, Lines 25-32).

Claim Rejections - 35 USC § 103

30. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

31. Claims 1 and 5-8 are rejected under 35 U.S.C. 103(a) as being unpatentable over Silvestrini (US 20020010510).

32. Regarding Claim 1, Silvestrini discloses an iris prosthesis system with diaphragms (Figure 4) that create an artificial pupil in the anterior section of the eye (Paragraph 136) and which are flexible and foldable (Paragraph 29) and therefore capable of being implanted using methods known in the art. Silvestrini does not explicitly disclose an iris prosthesis system comprising at least three diaphragms. However, it is well known in the art to ship and package three or more surgical devices, such as those taught by Silvestrini for the purpose of providing

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efficient use of packaging space and facilitating an easier transition from package to implantation. Therefore, it would have been obvious to one having ordinary skill in the art at the time of invention to include at least three diaphragms packaged in the iris prosthesis system for shipping and implantation individually or in combination.

33. Regarding Claim 5, Silvestrini discloses the diaphragm as consisting essentially of rigid planar elements 24 and 28 (Paragraph 153) that are divided on a fold line 38 (Figure 10) and there is an adhesive (“bondable”) connection of planar elements at the division by elastic polymers (Paragraph 153). This adhesive connection and folding mechanism make the device capable of being folded in half and unfolding to its original position due to its elasticity.

34. Regarding Claim 6, as best understood, Silvestrini discloses fold line 38 as being a straight line (Figure 10).

35. Regarding Claim 7, Silvestrini discloses the diaphragm as having a single fold line 38 across the diaphragm (Figure 10).

36. Regarding Claim 8, Silvestrini discloses the diaphragm as having two parallel joints 42 and 44 (Figure 13 and Paragraph 157) that are capable being folded at the joints.

37. Claims 1, 14, and 15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Barber (US 5489301).

38. Regarding Claim 1, Barber discloses an iris prosthesis system with diaphragms (Figure 1) that create an artificial pupil in the anterior section of the eye (Column 7, Lines 40-46) and which are flexible (Abstract) and therefore capable of being implanted using methods known in the art. Barber does not explicitly disclose an iris prosthesis system comprising at least three diaphragms. However, it is well known in the art to ship and package three or more surgical

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devices, such as those taught by Barber for the purpose of providing efficient use of packaging space and facilitating an easier transition from package to implantation. Therefore, it would have been obvious to one having ordinary skill in the art at the time of invention to include at least three diaphragms packaged in the iris prosthesis system for shipping and implantation individually or in combination.

39. Regarding Claim 14, Barber discloses the iris prosthesis system as having a symmetry of rotation about its optical axis and normal to its main plane (Figure 1), and a lens body 13 curved convex outward, a diameter setback 12, and an anchoring part 23 curved convex outward and having a greater diameter than both the lens body and diameter setback (Figure 2).

40. Regarding Claim 15, as best understood, Barber discloses the iris prosthesis system as having a lens body 13 that is greater in diameter than the anchoring part 18 “peripheral groove” (Figure 3 and Column 4, Lines 62-67).

41. Claim 16 is rejected under 35 U.S.C. 103(a) as being unpatentable over Hermeking (US 6221106).

42. Regarding Claim 16, Hermeking discloses the diaphragm as consisting of pigment dyed PMMA (Column 5, Lines 13-14) or soft acrylic (Column 5, Lines 15-16), but does not explicitly disclose the acrylate being hydrophilic. However, it is well known in the art to produce ocular implants from hydrophilic acrylates such as pHEMA for the purpose of providing a material compatible for ocular implantation. Therefore, it would have been obvious to one having ordinary skill in the art at the time of invention to substitute the implanted material for one selected from the group of materials known in the art to be biocompatible.

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Conclusion

43. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Schanzlin et al (US 20040073303) discloses a corneal insert system comprising at least three inserts packaged and implanted individually or in combination and further discloses the use of hydrophilic acrylates such as pHEMA for implantation in the human eye.

44. Any inquiry concerning this communication or earlier communications from the examiner should be directed to TIMOTHY GOSART whose telephone number is (571)270-7826. The examiner can normally be reached on Monday-Friday 7:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Quang Thanh can be reached on (571)272-4982. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/T. G./
Examiner, Art Unit 4118

/Quang D. Thanh/
Supervisory Patent Examiner, Art Unit
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